

Change in IRB Processes

Informed Consent IRB Approval Stamp

Beginning June 1, 2004, the IRB will implement a new procedure for Informed Consents. All projects initially approved from this date forward will have an IRB Approved stamp on the informed consent. Subjects are to sign only ICFs that have the IRB Approved stamp.

All studies that were initially approved prior to this date will follow the old procedure.

Informed Consent Version Control

A new version control system will also be implemented at this time. A simple Version 1.0, 2.0, 3.0... system will appear in the lower left footer of each page of the informed consent. All IRB approval letters will reference the Version # approved.

Notification of IRB Action

IRB Services will no longer be initiating a change order notifying staff that a new approved Informed Consent is now on the drive. An email will be sent to a system distribution list maintained by Corporate Support. Included on the distribution list are the PIs, study managers, project managers, site managers, site director, and admissions staff. If additional associates need to be added to the list, please contact Corporate Support.

If you have any questions, please contact me at 402-437-0570.

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